

97S-0163

JUL - 7 1997

Mr. Curtis Jacquot
Pacific BioLogic, Inc.
P.O. Box 520
Clayton, California 94517-0520

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Dear Mr. Jacquot:

This is in response to your letter to the Food and Drug Administration (FDA) dated May 8, 1997, in which you submitted revised text for a product brochure that describes the intended use of a number of dietary supplements that your firm intends to market.

In previous letters to your firm dated January 14, 1997 and March 21, 1997, we explained that section 403(r)(6) of Federal Food, Drug, and Cosmetic Act (the act) makes clear that a claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases may not be made under the authority of that section. Certain statements contained in the text you submitted suggest that PRE COLD PLUS and RESIST are intended for one or more of these purposes.

The product PRE COLD PLUS is promoted for use "to strengthen the body's own defenses against the common cold and flu infections" and is purported to be formulated to "enhance its ability to fight off modern viral infections." Furthermore, the suggested use of the product is "as soon as possible at the very first signs you recognize which could develop into a cold or flu. Continue to take until the symptoms are gone 24+ hours." These claims suggest that the intended use of this product is to treat, prevent or mitigate the symptoms of colds, the flu, and viral infections.

The product RESIST is promoted for use in "rebuilding its vital forces in order to prevent disease." The claim "to prevent disease" evidences that the product is intended for other than food use within the meaning of section 201(g)(1)(B) of the act.

These claims on the label or in the labeling of your products evidence that they are intended to prevent, cure, treat, or mitigate disease and that the products are subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

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Please contact us if we may be of further assistance.

Sincerely yours,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals

cc:

HFA-224 (w/incoming)

HFD-310

HFR-PA140

HFS-22 (CCO)

HFS-450 (r/f, OSN#52582)

HFS-456 (r/f, Moore w/cpy incoming)

r/d:HFS-456:RJMoore:5/29/97

revised per PDerfler:7/1/97

f/t:HFS-456:RJMoore:rjm:7/1/97:DocName:52582.OSN:Disc22